

REMARKS

Claims 1-45 are currently pending in this application. Claims 15-17 are allowed. Claims 1-14 and 18-45 stand rejected. Claims 22-24 have been cancelled. Claim 1, 4, 9, 18, 19, 35 have been amended.

Applicants thank the Examiner for indicating allowable subject matter.

Claim Rejections

I. Rejection 35 U.S.C. § 112 ¶1 (Enablement) :

The Examiner rejects Claim 1, 9-14 and 29-45 under 35 U.S.C. 112, first paragraph by alleging that the specification does not enable the preparation of the entire scope of the claimed compounds.

In support of his position the Examiner alleges

does in compounds “[T]he specificationdoes not provide any explanation or sources such that a person of ordinary skill could determine if a particular group is suitable to be a herbicidally effective derivative of CO₂H for the claimed structural formula. The specification at page 10 provides that the substituent R is defined as any salt, ester, etc.', however, the specification not provide sufficient guidance as to what is encompassed by the recitation the claim. In view of the lack of direction provided in the specification regarding starting materials, the lack of working examples and the general unpredictability of chemical reactions, it would take an undue amount of experimentation for one skilled in the art to make the claimed and therefore practice the invention.”

and then alleges that:

starting “The specification fails to enable the preparation of the entire scope of the claimed compounds...however there is no disclosure of the sources of materials needed to prepare compounds wherein R² is ((O)_jC(R¹⁵)(R¹⁶))_kR wherein R is a herbicidally effective derivative of CO₂H.”

Applicant's Response

The enablement requirement of § 112 is satisfied when an application describes a claimed invention in a manner that permits one of ordinary skill to practice it, without undue experimentation. (MPEP § 2164.01). The mere fact that *some* experimentation is required is insufficient to support an enablement rejection.

The Examiner contends it is undue experimentation for the skilled artisan to determine whether any given compound is “herbicidally effective”.

The Examiner then extrapolates from the contention above by alleging that Applicants have “not enabled preparation of the entire scope of the claimed compounds” and that presumably this is so because applicants have not described “starting materials” required to make every compound within the scope of the claim

With regard to the necessity to test or screen compounds using well known methods, the Federal Circuit has specifically validated the proposition that a disclosure that utilizes routine screening using well known procedures constitutes an enabling disclosure. Applicants would point the Examiner to *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F. 2d 1367, 231 U.S.P.Q. (BNA) 81 (Fed. Cir. 1986)

With respect to screening, the only permissible view of the evidence is that screening methods used to identify the necessary characteristics, including affinity, of the monoclonal antibodies used in the invention were known in the art and that the '110 patent contemplated one of those. At trial, Monoclonal's counsel stated "it is a procedure that was known in '78." We hold as a matter of law that the '110 patent disclosure is enabling.

The specification teaches the skilled artisan how to determine whether any compound is herbicidally effective in the Biological Examples of the Invention in Tests A through L beginning on page 72 and extending through page 142 of the specification. Further, even if such examples were not provided, Applicants submit that the term ‘herbicidally effective’ is art recognized and the methods used to determine if a compound is herbicidally effective are routine and just the sort of routine screening contemplated by *Hybritech*.

With respect to the question of un-recited embodiments or any supposed requirement that they are required to teach the making and requisite starting materials of every or even most compounds within the scope of the claim, Applicants would point the Examiner to *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 68 (Fed. Cir. 2003), *cert. denied*, 124 S.Ct. 2390 (U.S. May 24, 2004):

[A]s part of the quid pro quo of the patent bargain, the applicant’s specification must enable one of ordinary skill in the art to practice the full scope of the claimed invention. . . . That is not to say that the specification itself must necessarily describe how to make and use every possible variant of the claimed invention, for the artisan’s knowledge of the prior art and routine experimentation can often fill gaps, interpolate between embodiments, and perhaps even extrapolate beyond the disclosed embodiments, depending upon the predictability of the art. See *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366 [42 USPQ.2d 1001] (Fed. Cir. 1997) (“[A] specification need not disclose what is well known in the art.”); see also *Wands*, 858

F.2d at 736-37 (“Enablement is not precluded by some experimentation, such as routine screening.”).

Applicants respectfully submit that they have provided exhaustive teaching of how to make and use their invention in a manner sufficient to meet the standard set forth in *AK Steel*.

Such teaching is found in process Schemes 1-10 (pgs. 22-27 of the specification), synthesis Examples 1-5 (pgs. 27-33 of the specification) and Index Tables A-D (pgs 64-72). Any teaching which is not taught explicitly can only be characterized as mere gap filling contemplated by *AK Steel*. If the Examiner persists in this rejection Applicants would respectfully request that the Examiner explain why the patentability principles set forth in *Hybritech* and *AK Steel* are not applicable to Applicant’s invention. Otherwise Applicants respectfully request that the rejection be withdrawn.

II. Claim Rejections under 35 U.S.C. § 112 ¶2

The Examiner rejects Claims 1-14 and 18-45 under 35 U.S.C 112 second paragraph as allegedly being indefinite and provides the following grounds of rejection

1. “In claim 1, in the definition of R, it is not clear what is intended by "a herbicidally effective derivative of CO₂H". The specification does not provide sufficient explanation of the term.”

Applicant’s Response

As long as the boundaries of the claim are capable of being understood, the claim meets the requirements of the statute.

A “herbicidally effective derivative of CO₂H” is described in the specification at page 10, lines 21-28 as set forth below:

“a herbicidally effective derivative of CO₂H” when used to describe the substituent R in Formula I is defined as any salt, ester, carboxamide, acyl hydrazide, imidate, thioimide, amidine, acyl halide, acyl cyanide, acid anhydride, ether, acetal, orthoester, carboxaldehyde, oxime, hydrazone, thioacid, thioester, dithiolester, nitrile or any other carboxylic acid derivative known in the art which does not extinguish the herbicidal activity of the compound of Formula I and is or can be hydrolyzed, oxidized, reduced or otherwise metabolized in plants or soil to provide the carboxylic acid function, which depending upon pH, is in the dissociated or the undissociated form.”

The structure of any “herbicidally effective derivative of CO₂H” is constrained by the core structure of Formula I, the metes and bounds of which are clearly defined by other variables R¹, R³ and R⁴ attached to the core structure.

As noted above, a herbicidally effective derivative can be easily identified. The specification and the art provide ample guidance. As discussed in line 16 through 28 on page 10, because compounds of Formula I wherein R (and hence R²) is CO₂H are herbicidally active and their derivatives are susceptible to hydrolysis (to R being CO₂H) particularly in the presence of hydrolytic enzymes, these derivatives of Formula I are generally useful as herbicides. By analogy, salts of compounds of Formula I wherein R¹ is CO₂H, are appropriately recognized as biological equivalents that generally share the utility of the parent carboxylic acids. The same is true of Applicant's derivatives. The law does not require that Applicant's derivatives be more precisely defined than salts.

Any requirement to limit these derivatives would not appropriately protect the breadth of the invention that the Applicants have discovered, and would instead facilitate noninventive circumvention.

Similar claim language appears in granted U.S. patents. For example, US Patents 7,432,227, 7,314,849, 7,300,907, 7,291,580, 6,784,137 and 6,297,197 all recite "agriculturally acceptable derivatives of the carboxylic acid" as an element of in the claims. Applicants would submit these issued US Patents are presumptive proof that use of such terms in the claims does not render them indefinite. If the Patent Office would take the position that issued patents are not sufficient evidence that a claim term meets the statutory standard of clarity required under 35 U.S.C. § 112 ¶2 then Applicants respectfully request that this position be made of record.

2. "Claim 1 recites the limitation "provided that: (b) when R² is CH₂OR^a wherein R^a is H, optionally substituted alkyl or benzyl, then R³ is other than cyan" in page 145, lines 1819. There is insufficient antecedent basis for this limitation in the claim. The claim does not provide that R₂ can be represented by the term CH₂OR^a and there is no recitation of the term " R^a " in the claim before the exclusionary proviso. It is not clear, how an embodiment is excluded without being included in the claim."

Applicant's Response

In order to facilitate examination of this application, Applicants are limiting R³ to exclude "cyano". Basis for this amendment can be found in Embodiments 48 and 50 on page 16 of specification. This amendment obviates the need for proviso (b) in Claim 1.

3. Claim 1 recites the limitation "provided that: (e) when R¹ is cyclopropyl, then R is other than C(=W)N(R^b)S(O)₂-R^c-R^d wherein" in page 145, lines 24-31. There is insufficient antecedent basis for this limitation in the claim. The claim does not provide that

R can be represented by the term $C(=W)N(R^b)S(O)_2-R^c-R^d$ and there is no recitation of the terms " R^b , R^c , R^d " in the claim before the exclusionary proviso. It is not clear, how an embodiment is excluded without being included in the claim.

Applicant's Response

$C(=W)N(R^b)S(O)_2-R^c-R^d$ is within the scope of R when R^b , R^c and R^d are defined as recited in the proviso. There is no need for antecedent basis for R^b , R^c and R^d in the claim before the proviso, because R^b , R^c and R^d are used solely to define variables relevant to the expression $C(=W)N(R^b)S(O)_2-R^c-R^d$. Therefore, subject matter defined by proviso (e) clearly describes and subject matter to be removed from Claim 1.

When instant j and k are 0 and R is defined as a "herbicidally effective derivative" then the formula $C(=W)N(R^b)S(O)_2-R^c-R^d$ with the variables defined within the proviso is considered to remove any specific overlap with U.S. 5,324,710 (previously disclosed in an IDS).

4. "Claim 1 recites that limitation "provided that: (f) the compound of Formula I is other than diethyl 6-amino-5-nitro-2-phenyl-4-pyrimidinemalonate" in page 145, lines 32-33. There is insufficient antecedent basis for this limitation in the claim. The compound recited in (f) has the following structural formula: [structure]
In claim 1, the 4-position substituent R^2 is defined as $((O)_jC(R^{15})(R^{16}))_kR$, which does not appear to equate to "diethylmalonate group" of the excluded compound. Appropriate explanation and/or clarification are required."

Applicant's Response

The compound in the proviso corresponded to a compound of Formula I wherein R^1 is phenyl, R^3 is NO_2 , R^4 is NH_2 , and R^2 is $((O)_jC(R^{15})(R^{16}))_kR$ wherein R is a herbicidally effective derivative of CO_2H is properly interpreted to include this specific malonate ester derivative as described in Clark J., et al. *J. Chem. Soc. C* **1969**, 10, 1408-1412.

Proviso (f) has been removed in light of the amendments to Claim 1 to remove subject matter wherein R^1 is phenyl.

5. "Claim 2 recites the limitation " R^2 is ..., CH_2OR^{13} , $CH(OR^{46})(OR^{47})$, CHO , $C(=NOR^{14})H$, $C(=NNR^{48}R^{49})H$, $C(=O)N(R^{18})R^{19}$, $C(=S)OR^{50}$, $C(=O)SR^{51}$, $C(=S)SR^{52}$ or $C(=NR^{53})YR^{54}$ " in lines 2-4. There is insufficient antecedent basis for this limitation in the claim."

Applicant's Response

The specification provides examples of what functionalities are intended when R is a "herbicidally effective derivative of CO_2H ". These include any ether (p. 10, line 24:

CH₂OR¹³), acetal (p. 10, line 24: CH(OR⁴⁶)(OR⁴⁷)), carboxaldehyde (p. 10, line 24: CHO), oxime (p. 10, line 24: C(=NOR¹⁴)H), hydrazone (p. 10, line 24: (C(=NNR⁴⁸R⁴⁹)H), carboxamide (p. 10, line 23: C(=O)N(R¹⁸)R¹⁹), thioester (p. 10, line 24: C(=S)OR⁵⁰ or C(=O)SR⁵¹), dithiolester (p. 10, line 25: C(=S)SR⁵²) or imidate, thioimide, or amidine (C(=NR⁵³)YR⁵⁴).

These variables “add an additional element” to R² and further limit Claim 1 consistent with 35 U.S.C 112 ¶4.

III. Claim Rejections under 35 U.S.C. § 103:

The Examiner has rejected Claims 1-3, 10-14 and 29-45 as being unpatentable over Wolfgang et al. (DE 3807532) under 35 U.S.C. § 103. The Examiner alleges that:

The reference teaches a generic group of pyrimidine compounds, which embraces applicant's instantly claimed compounds. See formula (I) in page 2 wherein R₁ is haloalkyl. The reference discloses several compounds having a C₃ haloalkyl group in Table 1 (see starting page 21). The compounds are taught to be useful as herbicidal agents, see the abstract. The instant claims differ from the reference by a genus which encompasses the reference disclosed compounds. It would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of the genus taught by the reference, including those instantly claimed, because the skilled chemist would have the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as taught for the genus as a whole i.e., as herbicides. One of ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole. It has been held that a prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within a genus. *In re Susi*, 440 F.2d 442, 169 USPQ 423, 425 (CCPA 1971), followed by the Federal Circuit in *Merck & Co. v. Biocraft Laboratories*, 847 F.2d 804, 10 USPQ 2d 1843, 1846 (Fed. Cir. 1989).

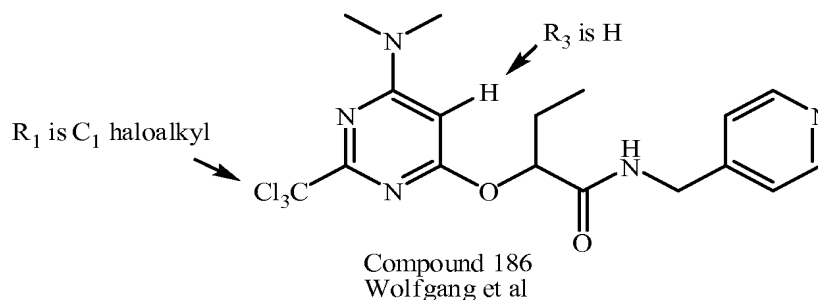
Applicant's Response

Compounds disclosed in Wolfgang et al. do not suggest the compounds of the present application. Contrary to the Examiner's assertion, the compounds of the present application are a separate and patentably distinct genus of compounds from Wolfgang et al.

The Examiner points to several compounds of Wolfgang Table 1 (starting at page 21) disclosing compounds containing R₁ being C₃ alkyl. However, Applicants draw the Examiner's attention to instant R⁴ defined as -N(R²⁴)R²⁵ or -NO₂ which is not disclosed by Wolfgang. The corresponding group of Wolfgang R₂ is “H, halogen, cyano, C₁-C₄ alkyl which is singly or multiply substituted with halogen, nitro, cyano, C₁-C₄ alkoxy, C₁-C₄

alkylthio or $\text{NR}_5\text{R}_6; \dots$ ". Wolfgang therefore does not suggest the instant definition of R^4 being $-\text{N}(\text{R}^{24})\text{R}^{25}$ or $-\text{NO}_2$.

Compound 186 in Table 1 from Wolfgang et al. mistakenly discloses R_2 being $-\text{N}(\text{Me})_2$ even though this functional group is not included in the generic definition for Wolfgang R_2 . However, even this compound does not render the instant invention obvious. First, Wolfgang R_1 is C_1 haloalkyl as opposed to Applicant's R^1 being cyclopropyl or isopropyl. Second, Wolfgang R_3 is H as opposed to Applicant's R^3 being halogen, nitro, OR^{20} , SR^{21} , or $-\text{N}(\text{R}^{22})\text{R}^{23}$.



The majority of the 392 compounds named in Wolfgang Table 1 contain compounds where R_2 is CH_3 (i.e. 222) or H (i.e. 99). This is supported by the disclosed herbicidal activity. For example pre-emergence herbicidal activity is reported in Table 2 of Wolfgang et al for compounds where R_2 is only CH_3 (i.e. compounds 8 and 10) or H. Also, post-emergence herbicidal activity is reported in Table 3 of Wolfgang et al for compounds where R_2 is only CH_3 (ie. compounds 8, 10 and 35) or H.

It is well known in the art of herbicide chemistry that the activity of organic compounds is a function of numerous factors relating to physical properties (such as size, shape, solubility, lipophilicity, etc.) and biochemical properties (such as transport, binding, metabolism, etc.). Given this complexity, the skilled artisan would not predict the activity of the compounds of the instant invention from the disclosure of Wolfgang et al. Even replacing a hydrogen or methyl as a substituent on the pyrimidine ring can have a substantial effect on the stereoelectronic profile of a molecule and its biological utility. Replacement of a hydrogen or methyl group with $-\text{N}(\text{R}^{24})\text{R}^{25}$ or $-\text{NO}_2$ to provide improved biological activity is not taught or suggested by Wolfgang et al and is therefore a non-obvious improvement over the disclosed reference genus.

Miscellaneous Items

I. Duplicate Claims:

The Examiner has warned that should Claims 32 and 33 be found allowable, Claims 41 and 42 will be objected to as substantial duplicates.

Applicant's Response

Although it is submitted that claims 41 and 42 differ in scope from claims 32 and 33, in order to facilitate prosecution, claims 41-42 have been canceled.

II. Potential Interference:

The Examiner has drawn Applicant's attention to U.S. Patent No. 7,300,907 and U.S. Patent Application Publication 2008/0091016 and characterizes these documents as "claiming subject matter that is substantially similar to that claimed herein". The Examiner states further that,

"unless applicants can demonstrate that the instant claims are patentably distinct from the claims in this US patent, the only way to overcome these patents is by way of interference proceedings or removal of the conflicting subject matter. See MPEP § 2306."

Applicant's Response

Applicants note that the specification and prosecution history of US 7,300,907 specifically identify Applicant's application as prior art. The Examiner's point is moot however as the currently amended claims exclude from the definition of R¹ "phenyl optionally substituted with 1-3 R⁷". However Applicants note that MPEP § 2306 does not require them to remove any subject matter.

In view of the foregoing, allowance of the above-referenced application is respectfully requested.

Respectfully submitted,

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